

REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed April 25, 2005 ("Office Action"). Claims 24-51 are pending in the application. Claims 24-51 are new. Support for the newly claimed subject matter may be found, for instance, in the claims as originally filed. In particular claim 24 has been amended to incorporate the subject matter of cancelled claim 2. Further support for the claimed subject matter may be found on page 12, lines 5-11 of the specification as filed. Other amendments have been made to correct minor informalities relating to grammar and translation errors. Applicant respectfully requests reconsideration of the rejection of the pending claims for the following reasons.

Claim Objections

The Office Action objects to claims 8, 12, 16-18, and 22-23 under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot refer back to another multiple dependent claim. Claims 8, 12, 16-18, and 22-23 have been canceled. New claims 24-51 are presented without multiple dependent claims that depend from other multiple dependent claims. Accordingly, the objection as to claim form must be withdrawn.

Indefiniteness -- 35 U.S.C. § 112, 2d para.

"A decision on whether a claim is invalid under § 112, 2d para., requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986).

The Office Action rejects claims 2-7, 13-15, and 19-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to steps (b) - (d) in canceled claim 2 (which is similar to pending claim 24) the Office Action states "[i]t is unclear if the protecting group in the peptide fragment is still present or has been deprotected." Office Action, page 3. However, the term "deprotecting" does

not denote removing the protecting group from the peptide fragment, but involves deprotection "of at least one reactive functional group." Thus, there is no inconsistency between steps (b) and (d) in claim 24.

With respect to canceled claims 13-15 and 19-21 (which are similar to claims 35-37 and 41-43, respectively), the Office Action states, "[t]he peptide fragment cannot be protected without modifying at least one amino acid in the peptide fragment." Office Action, page 3. Applicant respectfully submits that this statement in the Office Action confuses modification with protection as those terms are used in the pending claims. By way of explanation, a protecting group is introduced into a compound before the compound is subjected to a peptide bond, i.e., an amide bond formation reaction, in order to avoid undesirable side reactions. After the peptide bond formation reaction, the protecting group may then be eliminated or removed to obtain the desired peptide product. In contrast, modification changes the structure of the compound. Thus, it would be abundantly clear to a person having ordinary skill in the art that one does not necessarily modify a peptide fragment simply by protecting it.

Based on the foregoing, the rejection of the pending claims as being indefinite under 35 U.S.C. § 112, second paragraph, must be withdrawn as a person of ordinary skill in the art would understand what is claimed when the claims are read in light of the specification.

Anticipation -- 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Manual of Patent Examining Procedure § 2131 (8th ed., rev. 2, May 2004) (quoting Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The Office Action rejects claims 1-2, 9, and 11 under 35 U.S.C. § 102 (b) as being anticipated by Kitagawa et al. (2001 Chem. Pharm. Bull. 49(8): 958-963) ("Kitagawa").

Claims 1-2, 9, and 11 have been canceled. Claims 24, 31, and 33 correspond to canceled claims 2, 9, and 11, respectively. Kitagawa fails to teach or suggest every claim element of the claim 24. In particular, claim 24 requires the following sequence: "(b) deprotecting the

protecting group of at least one reactive functional group in the side chain of an amino acid or a non-amino acid A which is to be modified with a substituent R without cleaving the peptide fragment from the weak acid cleavable resin," and "(c) modifying the deprotected side chain with a substituent R." Although Kitagawa teaches making a "fully protected peptide," (Kitagawa, Chart 1, page 959) nothing in Kitagawa teaches modifying a deprotected side chain with a substituent R as required by the claims. Claim 24 is novel since Kitagawa fails to teach every limitation of the claim. Claims 25-40 and 46-51 are likewise novel as they depend from and incorporate the limitations of claim 24. Accordingly, the rejection based on anticipation under 35 U.S.C. § 102(b) by Kitagawa must be withdrawn.

The Office Action rejects claims 1-2, 5-7, and 12-13 under 35 U.S.C. § 102 as being anticipated by Kangawa et al. (EP 1197496) ("Kangawa").

Claims 1-2, 9, and 11 have been canceled. Claims 24, 31, and 33 correspond to canceled claims 2, 9, and 11, respectively. Kangawa fails to teach or suggest every claim element of the claims. Claim 24 requires the step of: "(a) preparing, on a weak acid-cleavable resin, a peptide main chain sequence of a peptide fragment." As discussed in the Office Action, "[t]he protected peptide resin was deprotected with anhydrous hydrogen fluoride (HF) in the presence of p-cresol thereby releasing the peptide, which was then purified." Office Action, page 5. Thus, Kangawa teaches using anhydrous hydrogen fluoride to cleave a peptide fragment instead of using a weak acid or a diluted strong acid. Claim 24 is novel since Kangawa fails to teach every limitation of the claim. Claims 25-40 and 46-51 are likewise novel as they depend from and incorporate the limitations of claim 24. Accordingly, the rejection based on anticipation under 35 U.S.C. § 102(b) by Kangawa must be withdrawn.

Obviousness -- 35 U.S.C. § 103

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally,

the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2143.03.

The Office Action rejects claims 1, 9-11 under 35 U.S.C. § 103 as being obvious over Kitagawa.

Claims 1, 9 to 11 have been canceled. Claims 31 to 33 correspond to canceled claims 9 to 11, respectively. It is noted that canceled claim 2 is not rejected as being obvious in view of Kitagawa. Pending claim 24 includes the limitations of cancelled claim 2. Accordingly, claim 24 is not obvious in view of Kitagawa for the same reasons that claim 2 was found non-obvious in view of Kitagawa in the Office Action and for the reasons presented below.

As discussed above, Kitagawa fails to anticipate the present claims. In particular, Kitagawa fails to teach or suggest the following sequence required by claim 24: "(b) deprotecting the protecting group of at least one reactive functional group in the side chain of an amino acid or a non-amino acid A which is to be modified with a substituent R without cleaving the peptide fragment from the weak acid cleavable resin," and "(c) modifying the deprotected side chain with a substituent R." Although the Office Action proceeds to address limitations of dependent claims 9-11 (which are similar to pending claims 31-33), there is no discussion in the Office Action as to how steps (b) and (c) of claim 24 are taught by Kitagawa. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." M.P.E.P. § 2143.03 (citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Thus, claim 24 is not obvious in view of Kitagawa. Claims 25-40 and 46-51 are likewise nonobvious as they depend from and incorporate the limitations of claim 24. Accordingly, the rejection for obviousness under 35 U.S.C. § 103 in view of Kitagawa must be withdrawn.

Applicant submits that this response addresses all of the issues raised in the Office Action and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. In the event any variance exists between the amount authorized to be charged to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
HUNTON & WILLIAMS LLP

By: 

Robert M. Schulman
Registration No. 31,196

Jeff B. Vockrodt
Registration No. 54,833

Dated: September 26, 2005

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W.
Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)
JBV/pam